

BOX MISSING PARTS-REISSUE

Attorney Docket No. 24856

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Group Art Unit: 1633

REUSER et al.

Serial No. 10/046,180

Filed: January 16, 2002

For: LYSOSOMAL PROTEINS PRODUCED IN THE MILK OF TRANSGENIC ANIMALS

PETITION UNDER 37 C.F.R. § 1.181 TO THE COMMISSIONER

Applicants, who have sufficient proprietary interests in the above captioned reissue application, submit this petition to the Commissioner to request that a lack of consent of all Assignees be accepted for this reissue application. This reissue application seeks to correct the inventorship of U.S. Patent 6,118,045.

Statement of Facts:

Upon personal interviews with each of the three inventors who have signed the Reissue Declaration as well as former Pharming employees, applicants through their counsel have discovered the misjoinder. The interviews indicated Dr. Frank R. Pieper had no role in the conception of the instantly claimed invention. Given these inventors relative lack of experience in determining inventorship under U.S. law and in order to be thorough and provide for the possibility that Dr. Pieper may nonetheless have been an inventor without the knowledge of the other three inventors, applicants repeatedly requested evidence of inventorship, e.g. lab notebooks, letters, etc. from Dr. Pieper. No documents were forthcoming.

Three of the named inventors proceeded to sign Reissue Declarations stating that they believe the original patent to be partly inoperative or invalid by reason of misjoinder of inventorship in the original patent. The error relied upon is that Dr. Frank R. Pieper did not invent the subject matter claimed in the original patent. This error arose without any deceptive intention on the part of the applicants. **RECEIVED**

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Further, three of the named assignees have signed Statements Under 37 CFR 3.73(b) and Consents of Assignee. These three assignees are Universiteit Leiden of the Netherlands, Academic Hospital of the Netherlands and Erasmus Universiteit of the Netherlands. The three assignees have sufficient proprietary interest in this matter.

Applicants sent the declaration for Dr. Pieper to Ms. Louise M. van den Bos of Erasmus Universiteit. Ms van den Bos, in turn, had two personal meetings with Dr. Pieper, during which he indicated he would not sign the declaration pending the outcome of negotiations between his employer Pharming Group N.V. (Pharming) who is the fourth assignee of this application, Erasmus Universiteit, and Genzyme Inc.

Pharming is the employer of Frank R. Pieper, who assigned his rights to Pharming in the original patent application number 08/700,760 for which a reissue application is being sought to correct the inventorship. It is important in this regard that Pharming is a Dutch corporation which filed for receivership protection under Dutch laws, while Genyzme Inc. is a U.S. corporation who had a relationship with Pharming and has announced their intention to acquire Pharming's assets in the press.

Pharming has refused to sign the Statement Under 37 CFR 3.73(b) and the Consent of Assignee. By refusing to sign as one of the assignees, not all of the applicants are applying for the reissue application to correct the inventorship. Remaining applicants maintain that this refusal of lack of consent is related to the refusal of the inventor Frank R. Pieper to sign the Inventors Declaration stating that is he not an inventor of U.S. Patent 6,118,045. This reissue application seeks to correct the inventorship of the original patent by revocing Frank R. Pieper as a named inventor thereof. Remaining applicants note that upon removal of Frank R. Pieper as an inventor, Pharming will lose all rights to the present inventive subject matter assigned to them by Dr. Pieper and accordingly will no longer be an assignee of this application.

The last known address of Pharming is P.O. Box 451, 2300 AL Leiden, The Netherlands.

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Applicants who have sufficient proprietary interest in this matter, as shown by the Statement Under 37 CFR 3.73(b) and the accompanying Consents of Assignee, thus file this reissue application to list the correct inventors. Applicants would suffer irreparable damage if said patent is held to be inoperative or invalid and the reissue application correcting the inventorship is not allowed to proceed.

As an additional factor in granting the petition, applicants would like to point out that this technology is currently in clinical trials helping children in at least two locations/hospitals to be treated for Pompe's Disease, a disease which previously had a 100% fatality rate prior to this treatment. Further to this, applicants are in active licensing negotiations with organizations who will be capable of developing a product and bringing it to market. Thus, it is imperative that this petition be granted to ensure the validity of a particularly important patent.

A petition fee of \$130.00 as set forth under S $1.17\mbox{(h)}$ is attached to this petition.

CONCLUSION

The Applicants, who have sufficient proprietary interest in this matter, as shown by the Statement Under 37 CFR 3.73(b) and the accompanying Consents of Assignee, thus petition the commissioner to allow this reissue application to be filed without the consent of the assignee Pharming.

Any questions regarding this petition should be directed to the undersigned attorneys.

Respectfully submitted, NATH & ASSOCIATES PLLC

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